States, for deposit to the special account ''Salaries and Expenses, Certification, Inspection and Other Services, Food and Drug Administration.''

[39 FR 11750, Mar. 29, 1974, as amended at 42 FR 27227, May 27, 1977; 48 FR 788, Jan. 7, 1983; 60 FR 56516, Nov. 9, 1995]

Subpart G—Records

§ 429.60 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 2 years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

PART 430—ANTIBIOTIC DRUGS; GENERAL

Subpart A—General Provisions

Sec.

Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 357, 371; 42 U.S.C. 216, 241, 262.

Subpart A—General Provisions

§ 430.3 Definitions applicable to all certifiable antibiotic drugs.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this chapter covering the certification of antibiotic and antibiotic-containing drugs.

(b) The term *Commissioner* means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purpose of the regulations for the certification of antibiotic and antibiotic-containing drugs.

(c) The term *act* means the Federal Food, Drug, and Cosmetic Act and amendments thereto. (52 Stat. 1040 *et seq.*; 21 U.S.C. 301–392).

(d) The term *U.S.P.* means the official Pharmacopeia of the United States, including supplements thereto. The term *N.F.* means the official National Formulary, including supplements thereto.

(e) The term *batch* means a specific homogeneous quantity of a drug.

(f) The term *batch mark* means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(g) The term *manufacture* does not include the use of a drug as an ingredient in compounding any prescription issued by a practitioner licensed by law to administer such drug.

[39 FR 18925, May 30, 1974]

§ 430.4 Definitions of antibiotic substances.

(a) The following are definitions of antibiotic substances:

(1) *Penicillin.* Each of the several antibiotic substances (e.g., penicillin F, penicillin G, penicillin X) produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum,* and each of

the same substances produced by any other means, is a kind of penicillin.

(2) *Streptomycin.* Each of the several antibiotic substances produced by the growth of *Streptomyces griseus,* and each of the same substances produced by any other means, is a kind of streptomycin.

(3) *Dihydrostreptomycin.* Each of the antibiotic substances produced by hydrogenation of streptomycin, and each of the same substances produced by any other means, is a kind of dihydrostreptomycin.

(4) *Chlortetracycline.* Each of the several antibiotic substances produced by the growth of *Streptomyces aureofaciens,* and each of the same substances produced by any other means is a kind of chlortetracycline.

(5) *Tetracycline.* Each of the several antibiotic substances produced by the hydrogenation of chlortetracycline, and each of the same substances produced by any other means, is a kind of tetracycline.

(6) *Chloramphenicol.* Each of the several antibiotic substances produced by the growth of *Streptomyces venezuelae,* and each of the same substances produced by any other means, is a kind of chloramphenicol.

(7) *Bacitracin.* Each of the several antibiotic substances produced by the growth of *Bacillus subtilis* var. Tracy, and each of the same substances produced by any other means, is a kind of bacitracin.

(8) [Reserved]

(9) *Amphotericin.* Each of the antibiotic substances produced by the growth of *Streptomyces nodosus,* and each of the same substances produced by any other means, is a kind of amphortericin.

(10) *Colistin.* Each of the antibiotic substances produced by the growth of *Bacillus polymyxa* var. *colistinus,* and each of the same substances produced by any other means, is a kind of colistin.

(11) *Cycloserine.* Each of the antibiotic substances produced by the growth of *Streptomyces orchidaceus,* and each of the same substances produced by any other means, is a kind of cycloserine.

(12) *Erythromycin.* Each of the antibiotic substances produced by the growth of *Streptomyces erythreus,* and each of the same substances produced by any other means, is a kind of erythromycin.

(13) *Gramicidin.* Each of the antibiotic substances produced by the growth of *Bacillus brevis,* and each of the same substances produced by any other means, is a kind of gramicidin.

(14) *Griseofulvin.* Each of the antibiotic substances produced by the growth of *Penicillium patulum* or *Penicillium griseofulvum,* and each of the same substances produced by any other means, is a kind of griseofulvin.

(15) *Kanamycin.* Each of the antibiotic substances produced by the growth of *Streptomyces kanamyceticus,* and each of the same substances produced by any other means, is a kind of kanamycin.

(16) *Neomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces fradiae,* and each of the same substances produced by any other means, is a kind of neomycin.

(17) *Novobiocin.* Each of the antibiotic substances produced by the growth of *Streptomyces niveus* (known also as *Streptomyces spheroides*), and each of the same substances produced by any other means, is a kind of novobiocin.

(18) *Nystatin.* Each of the antibiotic substances produced by the growth of *Streptomyces noursei,* and each of the same substances produced by any other means, is a kind of nystatin.

(19) *Oleandomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces antibioticus,* and each of the same substances produced by any other means, is a kind of oleandomycin.

(20) *Troleandomycin.* Each of the antibiotic substances produced by the triacetylation of oleandomycin, and each of the same substances produced by any other means, is a kind of troleandomycin.

(21) *Oxytetracycline.* Each of the antibiotic substances produced by the growth of *Streptomyces rimosus,* and each of the same substances produced by any other means, is a kind of oxytetracycline.

(22) *Paromomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces rimosus* var. *paromomycinus,* and each of the same

substances produced by any other means, is a kind of paromomycin.

(23) *Polymyxin.* Each of the antibiotic substances produced by the growth of *Bacillus polymyxa,* and each of the same substances produced by any other means, is a kind of polymyxin.

(24) *Plicamycin.* Each of the antibiotic substances produced by the growth of a variant of *Streptomyces plicatus,* and each of the same substances produced by any other means, is a kind of plicamycin.

(25) *Tyrothricin.* Each of the mixtures of antibiotic substances produced by the growth of *Bacillus brevis,* and each of the same mixtures of substances produced by any other means, is a kind of tyrothricin.

(26) *Vancomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces orientalis,* and each of the same substances produced by any other means, is a kind of vancomycin.

(27) [Reserved]

(28) *Gentamicin.* Each of the antibiotic substances produced by the growth of *Micromonospora purpurea,* and each of the same substances produced by any other means, is a kind of gentamicin.

(29) *Dactinomycin.* Dactinomycin is a specific kind of actinomycin produced by the growth of *Streptomyces parvullus* or the same antibiotic produced by any other means.

(30) *Candicidin.* Each of the heptaene antibiotic substances produced by the growth of *Streptomyces griseus* and each of the same substances produced by any other means is a kind of candicidin.

(31) *Cephalosporin.* Each of the antibiotic substances produced by the growth of *Cephalosporium acremonium,* and each of the same substances produced by any other means, is a kind of cephalosporin.

(32) *Lincomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces lincolnensis* var. *lincolnensis,* and each of the same substances produced by any other means, is a kind of lincomycin.

(33) *Demeclocycline.* Each of the antibiotic substances produced by removal of the 6-methyl group from chlortetracycline, and each of the same substances produced by any other means, is a kind of demeclocycline.

(34) *Clindamycin.* Each of the antibiotic substances produced by the 7-chloro-substitution of the 7(R)hydroxyl group of lincomycin, and each of the same substances produced by any other means, is a kind of clindamycin.

(35) [Reserved]

(36) *Capreomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces capreolus,* and each of the same substances produced by any other means, is a kind of capreomycin.

(37) *Rifamycin.* Each of the several antibiotic substances (e.g., rifamycin A, rifamycin B, rifamycin SV) produced by the growth of *Streptomyces mediterranei,* and each of the same substances produced by any other means, is a kind of rifamycin.

(38) *Spectinomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces spectabilis,* and each of the same substances produced by any other means, is a kind of spectinomycin.

(39) *Mitomycin.* Mitomycin is the antibiotic substance produced by the growth of *Streptomyces caespitosus,* and each of the same substances produced by any other means is a kind of mitomycin.

(40) *Doxorubicin.* Each of the antibiotic substances produced by the growth of *Streptomyces peucetius* var. *caesius,* and each of the same substances produced by any other means, is a kind of doxorubicin.

(41) *Bleomycin.* Each of the antibiotic substances produced by the growth of *Streptomyces verticillus* and each of the same substances produced by any other means is a kind of bleomycin.

(42) *Tobramycin.* A specific one of the antibiotic substances produced by the growth of *Streptomyces tenebrarius,* and the same substance produced by any other means, is tobramycin.

(43) *Amikacin.* Each of the antibiotic substances produced by the acylation of the 1-amino group of the 2-deoxystreptamine moiety of kanamycin A with L-(-)-γ)amino-α-hydroxybuyric acid, and each of the same substances produced by any other means is a kind of amikacin.

(44) *Vidarabine.* Vidarabine is a purine glycoside antibiotic substance produced by the growth of *Streptomyces antibioticus,* and each of the same substances produced by any other means is a kind of vidarabine.

(45) *Natamycin.* Each of the antibiotic substances produced by the growth of *Streptomyces natalensis,* and each of the same substances produced by any other means, is a kind of natamycin.

(46) *Daunorubicin.* Each of the antibiotic substances produced by the growth of *Streptomyces coeruleorubidus* and each of the same substances produced by any other means is a kind of daunorubicin.

(47) *Sisomicin.* A specific one of the antibiotic substances produced by the growth of *Micromonospora inyoensis,* and the same substance produced by any other means, is a kind of sisomicin.

(48) *Moxalactam.* 5-oxa-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[carboxy(4-hydroxyphenyl)acetyl]-amino]-7-methoxy-3-[[(1-methyl-1*H*-tetrazol-5-yl)thio]-methyl]-8-oxo-, disodium salt.

(49) *Cefoperazone.* Cefoperazone is a semi-synthetic antibiotic substance produced by the acylation of the amino group at the 7 position of 7-aminocephalosporanic acid with α-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-α-(4-hydroxyphenyl) acetic acid and introduction of a methylthiotetrazol group at the 3 position.

(50) *Netilmicin.* Netilmicin is a semi-synthetic antibiotic of the aminoglycoside group derived from sisomicin, and each of the same substances produced by any other means is a kind of netilmicin. It is D-Streptamine, 4-*O*-[3-amino-6-(aminomethyl)-3,4-dihydro-2*H*-pyran-2-yl]-2-deoxy-6-*O*-[3-deoxy-4-*C*-methyl-3-(methylamino)-β-L-arabinopyranosyl]-*N*^{1}-ethyl-, (2*S*-*cis*)-.

(51) *Cyclosporine.* Cyclosporine is a specific cyclic polypeptide consisting of 11 amino acids produced by the growth of *Cylindrocarpon lucidum* Booth or *Tolypocladium inflatum* Gams.

(52) *Cefonicid.* 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[(hydroxyphenylacetyl)amino]-8-oxo-3[[[1-(sulfomethyl)-1*H*-tetrazol-5yl]-thio]methyl]-, disodium salt, [6R-[6α7β(R*)]].

(53) *Clavulanic acid.* Clavulanic acid is an antibiotic substance produced by the growth of *Streptomyces clavuligerus* having the structure described as follows: *Z*-(2*R*, 5*R*)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, and each of the same substances produced by any other means, is a kind of clavulanic acid.

(54) *Ceftriaxone.* Ceftriaxone is a semi-synthetic antibiotic substance produced by the addition of S-2-benzothiazolyl-2-(2-aminothiazol-4-yl)-2-methoxyiminothioacetate to the 7 amino group of 7-amino-3-(2,5-dihydro-2 methyl-5,6-dioxo-1,2,4-triazin-3-yl)-thiomethyl-3-cephem-4-carboxylic acid.

(55) *Imipenem monohydrate.* Imipenem monohydrate is an antibiotic substance having the chemical structure described by the following name: [5*R*-[5α,6α,(R*)]]-6-(1-hydroxyethyl)-3-[[2-[(iminomethyl)amino]ethyl]thio]-7-oxo-1-azabicyclo[3.2.0]-hept-2-ene-2-carboxylic acid monohydrate.

(56) *Aztreonam.* [2*S*[2*alpha*,3*beta*(*Z*)]]-2-[[[1-(2-amino-4-thiazolyl)-2-[(2-methyl-4-oxo-1-sulfo-3-azetidinyl)amino]-2-oxoethylidene]amino]oxy]-2-methylpropanoic acid.

(57) *Sulbactam.* Sulbactam is a semi-synthetic antibiotic substance produced by the oxidation of the sulfur atom at the 4 position to its dioxide and the deamination at the 6 position of (2*S*,5*R*)-6-amino-3,3-dimethyl-7-oxo-4 thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid (6-APA).

(58) *Cefmenoxime.* Cefmenoxime is 5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-3-[[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-, [6*R*-[6-α,7-β(Z)]]-.

(59) *Cefixime.* Cefixime is a semi-synthetic antibiotic substance produced by the acylation of the amino group at the 7 position of 7-aminocephalosporanic acid with a β-[(2-amino-4-thiazolyl)(carboxymethoxy)imino] acetyl group and the introduction of a vinyl group at the 3 position.

(60) *Cefotiam.* Cefotiam is an antibiotic substance having the chemical structure described by the following

name: 7-(*R*)-[2-(2-amino-4-thiazol)acetamido]-3-[[[1-(2-dimethylamino)ethyl]-1*H*-tetrazol-5-y1] thio] methyl]-3-cephem-4-carboxylic acid.

(61) *Mupirocin*. Each of the antibiotic substances produced by the growth of *Pseudomonas fluorescens,* and each of the same substances produced by any other means, is a kind of mupirocin.

(62) *Cefmetazole.* Cefmetazole is an antibiotic substance having the chemical structure described by the following name: (6*R*-cis)-7-[[[cyanomethyl)thio]acetyl]amino]-7-methoxy-3-[[(1-methyl-1*H*- tetrazol-5-yl)thio]methyl]-8-oxo-5- thia-1-azabicyclo[4.2.0]oct-2- ene-2-carboxylic acid.

(63) *Cefpiramide.* Cefpiramide is an antibiotic substance having the chemical structure described by the following name: (6*R*, 7*R*)-7-[(*R*)-2-(4-hydroxy-6-methyl-nicotinamido)-2-(*p*-hydroxyphenyl)acetamido]-3-[[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

(64) *Clarithromycin*. Clarithromycin is 6-O-methylerythromycin A.

(65) *Azithromycin*. Azithromycin is an antibiotic substance having the chemical structure described by the following name: (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-*L*-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D*-*xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.

(66) *Cefprozil*. Cefprozil is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*R*)-7-[(*R*)-2-amino-2-(*p*-hydroxyphenyl)acetamido]8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is a mixture of the Z (cis) and E (trans) isomers in an approximate ratio of 9:1, respectively.

(67) *Idarubicin*. Idarubicin is an anthracycline antibiotic substance having the chemical structure described by the following name: 5,12-Naphthacenedione, 9-acetyl-7-[(3-amino-2,3,6-trideoxy-α-*L*-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,9,11-trihydroxy-(7*S*-*cis*).

(68) *Loracarbef*. Loracarbef is an antibiotic substance having the chemical structure described by the following name: (6*R*,7*S*)-7-[(*R*)-2-amino-2-phenylacetamido]-3-chloro-8-oxo-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid.

(69) *Rifabutin*. Rifabutin is an antibiotic substance having the chemical structure described by the following name: (9*S*,12*E*,14*S*,15*R*,16*S*,17*R*,18*R*,19*R*,20*S*,21*S*,22*E*, 24*Z*)-6,16, 18,20-tetrahydroxy-1′-isobutyl-14-methoxy-7,9,15,17,19,21,25-heptamethylspiro[9,4-(epoxypentadeca[1,11,13]trienimino)-2*H*-furo[2′,3′:7,8]naphth[1,2-d]imidazole-2,4′-piperidine]-5,10,26-(3*H*,9*H*)-trione-16-acetate.

(70) *Cefpodoxime proxetil*. Cefpodoxime proxetil is an antibiotic substance having the chemical structure described by the following name: (±)-1-Hydroxyethyl(+)-(6*R*,7*R*)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate,7²-(*Z*)-(*O*-methyloxime), isopropyl carbonate (ester).

(b) [Reserved]

[39 FR 18925, May 30, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §430.4, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 430.5 Definitions of master and working standards.

(a) *Master standards*—(1) *Penicillinand salts of penicillin*—(i) *Penicillin G* The term ''penicillin G master standard' means a specific lot of crystalline penicillin G that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin G working standard.

(ii) [Reserved]

(iii) *Penicillin V*. The term ''penicillin V master standard'' means a specific lot of crystalline penicillin V that is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin V working standard.

(iv)–(v) [Reserved]

(vi) *Methicillin*. The term ''methicillin master standard'' means a specific lot of crystalline methicillin that is designated by the Commissioner